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HM12/0619

EXAMINER

HARRIS, A

ART UNIT

PAPER NUMBER

1642

DATE MAILED:

06/19/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

[illegible]

Part of Paper No. 16

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DETAILED ACTION

Response to Amendment

1. Claims 1, 8, 9, 18-20, 24, 28, 35, 38, 40, 41, 43, 45, 47 and 50-60 are pending.

Claims 40, 43 and 60 have been amended.

Claims 20, 24, 28, 35, 38, 45 and 47, drawn to non-elected inventions are withdrawn from examination.

Claims 1, 8, 9, 18, 19, 40, 41, 43 and 50-60 are examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification

3. The disclosure is no longer objected to because the specification no longer contains embedded hyperlinks or other forms of browser-executable code listed on page 55.

Withdrawn Rejections

4. The rejection of claims 1, 8, 9, 18, 19, 51-56 and 60 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

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reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn in view of Applicants' arguments.

5. The rejection of claims 1, 40, 41, 43, 50 and 60 (listed in Paper number 14 in paragraph 12(a-c) under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of Applicants' arguments.

Claim Rejections - 35 U.S.C. § 101

6. The rejection of claims 1, 8, 9, 18, 19, 51-56 and 60 under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility, or a well established utility is withdrawn in view of Applicants' arguments.

Claim Rejections - 35 U.S.C. § 102

7. The rejection of claims 1, 18, 19, 50 and 59 under 35 U.S.C. 102(b) as being anticipated by Accession Number AA213817 (August 13, 1997) is withdrawn in light of Applicants' amendment.

7. The rejection of claim 60 under 35 U.S.C. 102(b) as being anticipated by Accession Number W86797 (July 1, 1996) is withdrawn in light of Applicants' amendment to the claim.

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8. The rejection of claims 50 and 59 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Number 5,880,102 (filed Jan. 17, 1995) is withdrawn.

Claim Rejections - 35 U.S.C. § 103

9. The rejection of claims 41 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent #5,880,102 is withdrawn.
10. The rejection of claims 43 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Accession #AA213817 is withdrawn.

Maintained Rejections

Claim Rejections - 35 U.S.C. § 112

11. The rejection of claim 40 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is maintained.

Applicants assert that there are working examples provided within the specification that show that the claimed nucleic acid sequences are expressed in specific tumor tissue samples. Applicants also assert that they "...have provided one of ordinary skill in the art with a set of tumor to test antisense compositions against, thus reducing the 'herculean' amount of

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experimentation to an amount that can only be characterized as routine.” This is found unpersuasive.

Within the purview of Applicants’ claim is *in vivo* therapy and the administration of a composition to a subject. As stated in paragraph number 11 of Paper number 14, mailed October 25, 2000 “[t]here needs to be an established role designated for sdph3.10 and sdp3.5 when the claims read on a composition geared toward treating.” The examples that Applicants have directed the Examiner’s attention do not evidence the use of this composition in the treatment of a subject with a tumor. Mere expression of molecules in a set of cells or in an organ does not enhance their credibility in regards to treatment. For the reasons cited and of record in paragraph #11 of Paper #14 the rejection is maintained.

12. The rejection of claims 9, 41, 57 and 58 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained and made.

a. Claims 9, 41, 57 and 58 are vague and indefinite in the recitation “...at least a portion...”. The Applicants argue that “[they] are permitted, but not required, to define commonly known words in the specification.” While this is true, Applicants are requested to define what amino acid sequences are encompassed by the “portion”. The term “portion” is not deemed indefinite, but what amino acids are encompassed by the term. Accordingly, one of ordinary skill in the art could interpret and portion as one amino acid residue.

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Claim Rejections - 35 U.S.C. § 102

13. The rejection of claims 1, 9, 18 and 19 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Number 5,880,102 (filed Jan. 17, 1995) is maintained. Applicant's argue that "the '102 patent does not describe the origin of SEQ ID NO:1 at all" and that Applicants' search revealed that the regions of SEQ ID NO:1 of the '102 patent that match region of SEQ ID NO:38 correspond to numerous vector sequences. This is not found persuasive. Applicants' claims do not exclude vector sequences, but embrace nucleic acid molecules that differ from the nucleic acid of SEQ ID NO:38 in codon sequence due to the degeneracy of the genetic code and complements of the said nucleic acid molecules. SEQ ID NO:1 of patent '102 discloses such a sequence and the expression vector contained within a host cell. Inherently, this nucleic acid complement would encode a portion of SEQ ID NO:39, a complement and the unique fragment excludes nucleic acid molecules completely composed of the nucleotide sequences of GenBank accession numbers U89672 or AA213817.

Conclusion

14. Claims 8, 43 and 60 are allowed.
15. Claims 8, 40, 41, 43 and 50-60 are free of the art.

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16. Claims 50-56 and 59 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris whose telephone number is (703) 306-5880. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:00 pm, with alternate Fridays off. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be

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reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Alana M. Harris, Ph.D.
Patent Examiner, Group 1642
June 14, 2001

Sheela Huff
SHEELA HUFF
PRIMARY EXAMINER